POLICY AND COMMUNICATIONS BULLETIN
THE CLINICAL CENTER

Medical Administrative Series

M99-1 26 February 1999

MANUAL TRANSMITTAL SHEET

SUBJECT: Participation of Clinical Research Volunteers in NIH Clinical Center Biomedical Research Protocols

1. Explanation of Material Transmitted: This bulletin transmits the policy of the Clinical Center regarding clinical research volunteers. The policy was approved by the Medical Executive Committee on 2 February 1999.

2. Material Superseded: None

3. Filing Instructions: "Other" Section

   Remove: None

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Physicians, Dentists and Other Practitioners Participating in Patient Care

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SUBJECT: Participation of Clinical Research Volunteers in NIH Clinical Center Biomedical Research Protocols

PURPOSE

- To ensure the safety of all research volunteers who participate in NIH Clinical Center research studies.
- To ensure that all research volunteers who participate in NIH Clinical Center research studies and receive financial compensation for such participation are registered in and compensated by the Clinical Research Volunteer Program.
- To provide a register and payment database for financially compensated clinical research volunteers.
- To provide a central repository for demographic information about prospective volunteers willing to participate in compensated clinical research studies that can be provided to clinical staff for recruiting purposes.
- To provide mechanisms for documenting and tracking participation in clinical research studies.

DEFINITIONS

Clinical research volunteers, for the purpose of this policy, include all subjects who receive financial compensation for participation in clinical research studies.

POLICY

- All clinical research volunteer medical records shall meet the Clinical Center standards for documentation.
- All clinical research volunteers seeking participation in compensated studies must report to the Clinical Research Volunteer Program (CRVP) office to be registered. Volunteers only have to register once provided the subject participates in a compensated study at least once in three years. Registration data includes name, social security or federal tax identification number and demographic information. This database also contains those protocols and procedures for which the volunteer has been compensated, the amount and date of compensation.
- Principal investigators must authorize participation, using MIS, each time a subject will participate in a new protocol. Principal investigators authorize participation of each clinical research volunteer based on an evaluation of the volunteer that includes a review of previous study involvement. This review shall occur prior to the volunteer's participation in a protocol.
- MIS enables principal investigators to retrieve the subject's prior participation in Clinical Center research studies.
- Principal investigators are responsible for familiarity with and use of MIS in reviewing a volunteer's prior participation.
- All medical orders and procedures such as blood draws, pharmaceuticals including investigational agents, radiation and radionuclide procedures, shall be ordered and/or recorded in MIS.
- Procedures must be documented in the medical record, either in the progress notes, or as a MIS entry at time of performance.
- The IRB and Institute Clinical Director shall approve compensation amounts and schedules for each protocol.
- Only the Clinical Research Volunteer Program is authorized to financially compensate clinical research volunteers.
- Clinical research volunteers deemed by a Principal Investigator to be inappropriate or unacceptable for participation in any research protocol (e.g., because of falsifying medical information, presenting a danger to themselves or others, or exhibiting threatening or coercive behavior) may lose the privilege of participating in the Clinical Research Volunteer Program.

PROCEDURES

A. Principal Investigators' Responsibilities

1. Principal Investigators or their designees are responsible for ensuring that research volunteers enrolling in studies for which they will be financially compensated are registered with the CRVP office before participating in a protocol. In the case of off-site volunteers or those who arrive before or after normal business hours, forms are available from the CRVP office that can be completed by the volunteer and returned to CRVP by the Principal Investigator.

2. Principal Investigators or their designees are responsible for evaluating and reviewing prospective volunteers' current and previous protocol participation as part of past medical history. MIS retrieval screens shall be used for subjects who have participated in prior Clinical Center protocols.

3. Principal Investigators or their designees shall enter the protocol and procedure information into the medical record either in the progress notes or as a MIS entry at time of performance as well as a copy of the signed consent form.

4. Principal Investigators or their designees shall complete an inpatient or outpatient payment visit report via MIS according to the compensation approved by the IRB and Institute Clinical Director. Payment may be requested only for participation in protocols for which the volunteer is listed in MIS and for procedures that have been documented in MIS or the medical record.

5. Principal Investigators will notify the Director, Clinical Research Volunteer Program and file an incident report on any research volunteer deemed inappropriate or unacceptable for participation in any compensated clinical research protocols. The incident report will note date and circumstances in question (see B.4).

B. Clinical Research Volunteer Program Responsibilities

1. Prior to taking part in their first research protocol, all clinical research volunteers seeking participation in studies offering financial compensation will report to the CRVP office to register. Volunteers have to register only once with the Clinical Research Volunteer Program provided the subject participates in a compensated study at least once in three years.

2. At registration, the CRVP will obtain demographic information from the volunteer, enter same in the data base and request identification to validate the information for compensation purposes. This information will be verified each time the volunteer is compensated by the CRVP.

3. CRVP staff shall enter protocol numbers, dates and procedures into the CRVP data base and process payments for the clinical research volunteers.

4. Any incident report submitted by a Principal Investigator or his designee concerning a clinical research volunteer deemed inappropriate or unacceptable will be reviewed and discussed by CRVP Advisory Committee. If the CRVP Advisory Committee agrees that a volunteer should lose his/her privilege to be a volunteer in financially compensated studies, appropriate notification on MIS will be available to all Principal Investigators.

5. CRVP staff shall provide a monthly report to Clinical Directors and Institute Administrative Officers or their designees. This monthly activity report will include the names of the volunteers, the protocols in which the volunteers participated, and the amount of compensation processed for each volunteer as well as the total monthly compensation charged to institute common account numbers (CANs). Two categories of volunteers are not reflected in this report: student volunteers here on long term protocols and volunteers who are compensated by issuance of a CRVP voucher. These categories are reported to the Institute by other means.